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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,138	09/23/2003	Indukumar G. Shah	MCP-5013	7577

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EXAMINER	
QAZI SABIHA NAIM	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
01/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/671,138	SHAH ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *8-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *8-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action

Claims 1-6 and 8-14 are pending. No claim is allowed. Amendments are entered.

Summary of this Office Action dated January 12, 2010

1. 35 USC § 103(a) Obviousness Rejection
2. Response to Remarks
3. Conclusion
4. Communication

Claim Rejections - 35 USC § 103—First Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be *obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patent ability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patent ability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 and 14 are rejected under 35 U.S.C. 103(a) as obvious over SUNSHINE (US Patent 4,486,436), TENCZA et al. (US Patent 4,943,565), Remington's Pharmaceutical Sciences Page 1837 and SCHROEDER et al. (US Patent 6,602,520).

Applicant Claims

- Applicant claim (1) is drawn to a solid pharmaceutical dosage form comprising caffeine, a disintegrant selected from the group consisting of sodium starch glycolate, crosslinked carboxymethylcellulose, and mixtures thereof, and a

cephalagic, wherein said caffeine is in the form of uncoated **ungranulated** particles having an average particle size of about 70 to 600 microns, and wherein at least 95 % of said caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Determining the scope and contents of the prior art (MPEP 2141.01)

SUNSHINE (US Patent 4,486,436) teaches analgesics and anti-inflammatory compositions comprising caffeine (3,7-dihydro-1,3,7-trimethyl-1H-purine-2,6-dione) and novel analgesic and anti-inflammatory compositions for use in eliciting an analgesic or anti-inflammatory response, said compositions comprising caffeine together with a selected non-narcotic analgesic/nonsteroidal anti-inflammatory drug or a selected narcotic analgesic, or both. When used in combination with the selected drugs, **caffeine enhances** the analgesic or anti-inflammatory response and also hastens its onset. (see the abstract). The reference teaches a composition of selected non-narcotic analgesics/nonsteroidal anti-inflammatory drugs, which differ substantially in chemical structure from aspirin, phenacetin and acetaminophen, and which have significantly different biological profiles therefrom, can be advantageously formulated into novel pharmaceutical compositions together with c**affeine** and administered to mammals, especially

humans, to not only elicit a more potent analgesic or anti-inflammatory response but also to evoke such response more rapidly than possible by administration of the analgesic or anti-inflammatory agent alone. See lines 44-55 in column 6. Suitable disintegrators can include, without limitation, starch, methylcellulose, agar, bentonite, cellulose, wood products, alginic acid, guar gum, citris pulp, **carboxymethylcellulose** and sodium lauryl sulfate. See lines 34-60 in column 21. See the entire document especially lines 1-36 in column 5, lines 24-32 in column 6, examples and claims.

TENCZA et al. teaches tablets containing, in combination, aspirin, acetaminophen and caffeine having improved dissolution rates. The combination of aspirin, acetaminophen and caffeine is popular in analgesic preparations and finds widespread use, particularly in over-the-counter (O.T.C) products. Moreover, a widely used dosage form for delivering this combination drug is tablet. Since these products are also likely to be subjected to elevated temperatures while in storage in warehouses and in homes, it has become customary in course of manufacturing such tablets to store them at elevated temperatures for extended periods of time to test their stability and the in-vitro availability of the active ingredients; i.e., **aspirin,**

acetaminophen and caffeine for pharmaceutical action. One method for measuring the latter has been to measure the dissolution rates of the tablets. If the tablets meet a certain standard for dissolution rate, the active ingredients should be available for absorption into the blood stream within an acceptable period of time after ingestion.

The dissolution rates of tablets containing aspirin, acetaminophen and caffeine can be improved by incorporating a low-substituted hydroxypropylcellulose in sufficient amount to serve as a secondary disintegrant. See the entire document especially abstract, lines 5-40 in column 3, examples and claims.

Remington's Pharmaceutical Sciences Reference teaches The reference Remington's Pharmaceutical Sciences clearly teaches that disintegrants is a substance or a mixture of substances, added to a tablet to facilitate its breakup or disintegration after administration. It teaches materials serving as disintegrating agents which include cellulose and crosslinked polymers. It teaches sodium starch glycolate as disintegrant. It further teaches that factors other than the presence of disintegrants can effect significantly the disintegration time of compressed tablets. The binder, tablet hardness and the lubricant have been shown to influence the disintegrate time.

SCHROEDER et al. teaches rapidly disintegrating preparations containing at least one active pharmaceutical ingredient and at least one excipient can be obtained. It teaches ibuprofen, caffeine and disintegrating agent carboxymethylcellulose. See the entire document especially abstract, line 20-30 in column 3, line 1 in column 4, lines 3-13 in column 5.

Ascertaining the differences between the prior art and the claims at issue (MPEP 2141.012)

Presently claimed invention differs in claiming specific solubility.

Finding of Prima Facie Obviousness, Rational and Motivation obviousness or nonobviousness (MPEP 2142-2143)

It would have been obvious to one skilled in the art at the time the invention was made to prepare additional beneficial solid pharmaceutical compositions having good dissolution rate and synergism containing active and useful drugs in combination **with caffeine and a disintegrant** because prior art teaches that by the addition of caffeine synergistic results are obtained and second disintegrant is added to improve the dissolution rate. Motivation has been provided by both the references cited above because disintegrant carboxymethylcellulose is taught by SUNSHINE. Furthermore, Remington's Pharmaceutical Sciences clearly teaches that disintegrants is a substance or a mixture of substances, added to a tablet to facilitate its breakup or disintegration after administration. It teaches materials serving as disintegrating agents which include cellulose and crosslinked polymers. It teaches sodium starch glycolate as disintegrant. It further teaches that factors

other than the presence of disintegrants can effect significantly the disintegration time of compressed tablets. The binder, tablet hardness and the lubricant have been shown to influence the disintegrate time. SCHROEDER teaches the preparation of rapidly disintegrating tablets.
Since prior art teaches the preparation of rapid disintegrating tablets by using the same ingredients and teaches all the factors which influence the disintegration so at the time the invention was filed it would have been obvious to prepare such tablets.

No criticality and/or unexpected results are noted.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Arguments

Applicants' arguments, filed on 9/24/2009, have been fully considered. Rejections not reiterated from previous office actions are hereby withdrawn. The rejections cited above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

- Applicant's arguments were fully considered but are not found persuasive therefore all the rejections are maintained. The amendments "ungranulated" does not overcome the prior art of record.

- TENCZA et al. (US '565) **teach 80% of the caffeine in their caffeine composition tablet dissolves within 5 minutes using a USP paddle apparatus rotated at** 50 rpm (figure 1 and pages 20-21). It is noted that Tencza et al. have adapted a dissolution rate such that at least 75% of the caffeine- acetaminophen tablet dissolves in under 45 minutes (page 21). Amended claim 1 is considered obvious because it would be obvious that at least 95% of the caffeine in the caffeine composition tablet of Tencza et al. would be dissolved within 5 minutes since the reference teaches that at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes. Presently claimed invention has been taught by the prior art.
- Applicant argues that Tenzca et al. (CA 1,336,687) does not teach the presently claimed invention. Examiner disagrees because the references teach caffeine and acetaminophen tablet compositions (abstract). The caffeine is uncoated and granular with a particle size between 20 mesh to 100 mesh (pages 11 and 23). The caffeine and acetaminophen tablet also comprises a disintegrant, such as crospovidone XL-20 (see page 9; and page 15, example 1). It is noted that crospovidone is well known in the pharmaceutical arts as crosslinked polyvinylpyrrolidone. The tablet is made via compression (page 23). The acetaminophen is granular (page 23).

Applicant is using the same amount of caffeine as used by all the cited references.

- Rejection over SUNSHINE et al. ' 436 is maintained for the same reasons as set forth in the previous office action and for the reason cited above for other rejections.
- Claimed invention as amended is still considered obvious over the prior art and is inherently taught by the prior art of record.

Specification disclosed one example on page 4 where 65 mgs of caffeine is used. There is no showing that 95% of caffeine dissolves in the example.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will

be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

COMMUNICATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612